



Billing Code 4410-09-M

**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**[Docket No. DEA-353]**

**Proposed Adjustment of the Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2012**

**AGENCY:** Drug Enforcement Administration (DEA), Department of Justice.

**ACTION:** Notice with request for comments.

**SUMMARY:** This notice proposes to adjust the 2012 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

**DATES:** Electronic comments must be submitted and written comments must be postmarked on or before *[INSERT 30 DAYS FROM DATE OF PUBLICATION]*. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

**ADDRESSES:** To ensure proper handling of comments, please reference “Docket No. DEA-353” on all electronic and written correspondence. DEA encourages all comments be submitted electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. An electronic copy of this document is also available at the <http://www.regulations.gov> Web site for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to [www.regulations.gov](http://www.regulations.gov) will be posted for public review and are part of the official docket record. Should you, however, wish

to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, VA 22152.

**FOR FURTHER INFORMATION CONTACT:** John W. Partridge, Chief, Liaison and Policy Section, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone: (202) 307-4654.

**SUPPLEMENTARY INFORMATION:**

**Posting of Public Comments**

Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov> and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted

within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

### **Background**

On December 12, 2011, DEA established the assessment of annual needs for 2012 for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, pursuant to 21 U.S.C. 826(a) and 21 CFR 1315.11 (76 FR 77252). That Notice indicated that DEA would adjust the assessment of annual needs at a later date, if necessary, as provided in 21 CFR 1315.13.

DEA now proposes to adjust the established assessment of annual needs for 2012 for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. In proposing the adjustment, DEA has taken into account the criteria that DEA is required to consider in accordance with 21 CFR 1315.13. DEA proposes the adjustment of the assessment of annual needs for 2012 by considering: (1) changes in demand, changes in the national rate of net disposal, and changes in the rate of net disposal by the registrants holding individual manufacturing or import quotas for the chemical; (2) whether any increased demand or changes in the national and/or individual rates of net disposal are temporary, short term, or long term; (3) whether any increased demand can be met through existing inventories, increased individual

manufacturing quotas, or increased importation without increasing the assessment of annual needs; (4) whether any decreased demand will result in excessive inventory accumulation by all persons registered to handle the particular chemical; and (5) other factors affecting the medical, scientific, research, industrial, and importation needs in the United States, lawful export requirements, and reserve stocks, as the Administrator finds relevant.

Other factors that DEA considered include trends as derived from information provided in applications for import, manufacturing, and procurement quotas and in import and export declarations. The inventory, acquisition (purchases), and disposition (sales) data as provided by DEA registered manufacturers and importers reflects the most current information available to DEA at the time of publication of this Notice.

### **Analysis**

In determining whether to propose adjustments to the 2012 assessment of annual needs, DEA considered the total net disposals (*i.e.*, sales) of the list I chemicals for the current and preceding two years, actual and estimated inventories, projected demand (2012), industrial use, and export requirements from updated data provided by DEA registered manufacturers and importers in procurement quota applications (DEA 250), manufacturing quota applications (DEA189), import quota applications (DEA 488), declarations for import and export, and other information. Data considered included data submitted to DEA after the initial assessment of annual needs had been established. DEA notes that the inventory, acquisition (purchases), and disposition (sales) data proved by DEA registered manufacturers and importers reflects the most current information available. In developing the proposed 2012 revision, DEA has used the calculation methodology described previously in the 2010 and 2011 assessment of annual needs

(74 FR 60294 and 75 FR 79407, respectively).

As of June 6, 2012, DEA registered manufacturers of dosage form products containing pseudoephedrine requested quota for 322,385 kg of pseudoephedrine. DEA registered manufacturers of pseudoephedrine reported sales totaling approximately 189,030 kg in 2010 and 268,669 kg in 2011; this represents a 30 percent increase in sales reported by these firms from 2010 to 2011. Additionally, DEA considered information on trends in the national rate of net disposals from sales data provided by IMS Health. The initial assessment of annual needs was based on data received by DEA as of October 17, 2011. Based on the updated information provided to DEA as of June 6, 2012, DEA is proposing to increase the 2011 assessment of annual needs for pseudoephedrine from 258,000 kg to 278,000 kg.

As of June 6, 2012, DEA registered manufacturers of dosage form products containing ephedrine requested quota for 4,221 kg of ephedrine (for sale) in 2012. DEA registered manufacturers of ephedrine reported sales totaling approximately 1,598 kg in 2010 and 3,158 kg in 2011; this represents a 49 percent increase in sales reported by these firms from 2010 to 2011. Additionally, DEA considered information on trends in the national rate of net disposals from sales data provided by IMS Health. The initial assessment of annual needs was based on data received by DEA as of October 17, 2011. Based on the updated information provided to DEA as of June 6, 2012, DEA is proposing to increase the 2012 assessment of annual needs for ephedrine (for sale) from 4,000 kg to 4,300 kg.

As of June 6, 2012, DEA registered manufacturers of phenylpropanolamine (for sale) requested quota for 7,763 kg of phenylpropanolamine (for sale). DEA registered manufacturers of phenylpropanolamine reported sales totaling approximately 4,790 kg in 2010 and 5,289 kg in

2011; this represents a nine percent increase in sales reported by these firms from 2010 to 2011.

DEA notes that phenylpropanolamine is sold primarily as a veterinary product and is not approved for human consumption. IMS Health's NSP Data does not capture sales of phenylpropanolamine to veterinary channels and is, therefore, not considered. The initial assessment of annual needs was based on data received by DEA as of October 17, 2011. DEA is proposing to increase the 2012 assessment of annual needs for phenylpropanolamine (for sale) from 5,200 kg to 5,800 kg.

As of June 6, 2012, the data provided to DEA for review of phenylpropanolamine (for conversion) and ephedrine (for conversion) demonstrated no significant changes in demand or net disposals. DEA has thus determined that the assessment of annual needs for these chemicals – phenylpropanolamine (for conversion) and ephedrine (for conversion) – shall remain unchanged.

The Administrator, therefore, proposes the following adjustment of the 2012 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine as follows:

List I Chemicals	2012 Assessment of Annual Needs	Proposed adjustment to the 2012 assessment of annual needs
Ephedrine (for sale)	4,000 kg	4,300 kg
Phenylpropanolamine (for sale)	5,200 kg	5,800 kg
Pseudoephedrine	258,000 kg	278,000 kg
Phenylpropanolamine (for conversion)	26,200 kg	No Change
Ephedrine (for conversion)	12,000 kg	No Change

In finalizing the adjustment of the 2012 assessment of annual needs for ephedrine,

pseudoephedrine, and phenylpropanolamine, DEA will consider any additional changes in demand, changes in the national rate of net disposal, or changes in the rate of net disposal by the registrants holding individual manufacturing or import quotas for the chemical, in accordance with 21 CFR Part 1315.

### **Comments**

Pursuant to 21 CFR 1315.13, any interested person may submit written comments on or objections to these proposed determinations. Based on comments received in response to this Notice, the Administrator may hold a public hearing on one or more issues raised. In the event the Administrator decides in her sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the Federal Register. After consideration of any comments and after a hearing, if one is held, the Administrator will publish in the Federal Register a Final Order determining any adjustment of the assessment of annual needs.

Dated: July 13, 2012

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Michele M. Leonhart  
Administrator

[FR Doc. 2012-17522 Filed  
07/17/2012 at 8:45 am; Publication  
Date: 07/18/2012]